

FLEXIBLE EXPANDABLE STENT

RELATED APPLICATIONS

[0001.] This application is a continuation of Ser. No. 09/337,629 filed June 21, 1999, which is a continuation of Ser. No. 09/026,099 filed February 19, 1998 (now U.S. Patent 5,972,018), which is a continuation of Ser. No. 08/881,594 filed June 24, 1997 (now U.S. Patent 5,843,120), which is a continuation of Ser. No. 08/782,467 filed Jan. 10, 1997, now abandoned, which is a continuation of Ser. No. 08/457,354, filed May 31, 1995 (now U.S. Pat. No. 5,733,303), which is a continuation of Ser. No. 08/282,181 filed Jul. 28, 1994 (now abandoned) and a continuation-in-part of Ser. No. 08/213,272, filed Mar. 17, 1994 (now U.S. Pat. No. 5,449,373).

FIELD OF THE INVENTION

[0002.] The present invention relates generally to stents for implanting into a living body.

BACKGROUND OF THE INVENTION

[0003.] Various stems are known in the art wherein, for the present application, the term "stent" indicates a device, made of body-compatible material, which is utilized to widen a blood vessel, or other orifice in the body, and to maintain the resultant size of the lumen. Typically, the stent is delivered to the desired location in the body with an inflatable balloon and, when the balloon is inflated, the stem expands, thereby widening the orifice. Other mechanical devices which cause expansion of the stent are also utilized.

[0004.] Exemplary patents in the field of stents formed of wire are: U.S. Pat. No. 5,019,090 to Pinchuk, U.S. Pat. No. 5,161,547 to Tower, U.S. Pat. No. 4,950,227 to Savin, et al., U.S. Pat. No. 5,314,472 to Fontaine, U.S. Pat. No. 4,886,062 and U.S. Pat. No. 4,969,458 to Wiktor and U.S. Pat. No. 4,856,516 to Hillstead. Stems formed of cut stock metal are described in: U.S. Pat. No. 4,733,665 to Palmaz, U.S. Pat. No. 4,762,128 to Rosenbluth, U.S. Pat. No. 5,102,417 to Palmaz and Schatz, U.S. Pat. No. 5,195,984 to Schatz and WO 91FR013820 to Meadox.

[0005.] The stents described in U.S. Pat. No. 5,102,417 to Palmaz and Schatz have expandable tubular grafts connected together with a flexible connector. The grafts are formed of a plurality of slots disposed parallel to the longitudinal axis of the tube. The flexible connectors are helical connectors. Since the tubular grafts are relatively rigid, the flexible connectors are needed so that the stents can bend when being fed through a curved blood vessel. When the stents of U.S. Pat. No. 5,102,417 expand, the grafts expand radially and, consequently, shrink longitudinally. However, at the same time, the helical connectors twist. The twisting motion is most probably harmful to the blood vessel.

[0006.] U.S. Pat. No. 5,195,984 to Schatz describes a similar stent but with one straight connector, parallel to the longitudinal axis of the tubular grafts, between tubular grafts. The straight member removes the twisting motion; however, it is not a very strong connector.

SUMMARY OF THE PRESENT INVENTION

[0007.] In accordance with embodiments of the present invention, a stent for implanting in the body to hold open a blood vessel, includes a body-compatible metal mesh defining a tube having adjacent contiguous cells, the cells having walls which are also the walls of adjacent cells. Each of the plurality of cells includes a pair of facing loops, each facing loop having a curved apex generally aligned along the longitudinal axis. Each facing loop has a first end and a second end that are generally aligned along the circumferential axis, each of the facing loops adapted to open further upon radial expansion of the stent which tends to foreshorten the stent longitudinally. Each of the plurality of cells further includes a pair of curved flexible links which connect the adjacent ends of the pair of facing loops to complete each of the plurality of cells, the pair of curved flexible links made of a metal which, upon expansion of the stent, bend to substantially offset foreshortening along the longitudinal axis.

[0008.] The pair of facing loops and the curved flexible links are disposed and adapted to cooperate so that the tube, when unexpanded, can flex as it is moved through curved blood vessels to a site where it is to be expanded and so that, when the stent is expanded in a curved

vessel, at that site, as compared to each other, cells on the outside of the curve are open in length, but narrow in width as compared to cells on the inside of the curve which are short in length but increased in width. This results in a more constant stent cell area between the inside and the outside of the curve than would otherwise occur. Consequently, when the stent is coated with a medicine the compensation results in a more even dose being applied to the inside wall of the lumen, avoiding the possibility that a toxic dose is supplied at one area while a less than effective dose is applied to another area

BRIEF DESCRIPTION OF THE DRAWINGS

[0009.] The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

[0010.] FIG. 1 is an illustration of a patterned stent, constructed and operative in accordance with a first preferred embodiment of the present invention;

[0011.] FIG. 2 is an illustration of the pattern of the stent of FIG. 1;

[0012.] FIG. 3 is an illustration of the stent of FIG. 1 in a bent position;

[0013.] FIG. 4 is an illustration of the stent of FIG. 1 in an expanded format;

[0014.] FIGS. 5A and 5B are illustrations of the changes in the patterns of the stent of FIG. 1 due to expansion;

[0015.] FIG. 6 is a schematic illustration of a second embodiment of the pattern for a stent;

[0016.] FIG. 7 is an illustration of a third embodiment of the pattern for the stent; and

[0017.] FIG. 8 is an illustration of the pattern of FIG. 7 in an expanded format.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0018.] Reference is now made to FIGS. 1-4 which illustrate a first embodiment of a stent, constructed and operative in accordance with the principles of the present invention. FIG. 1 illustrates the stent in its non-expanded form, FIG. 2 illustrates the pattern of the stent, FIG. 3 illustrates it in a partially bent position and FIG. 4 illustrates it in an expanded form. As shown in

FIG. 3, the stent 30 defines a longitudinal aperture 80 having a longitudinal axis or longitudinal extension 79.

[0019.] The stent of the present invention is a tube whose sides are formed into a plurality of each of two orthogonal meander patterns which patterns are intertwined with each other. The term "meander pattern" is taken herein to describe a periodic pattern about center line and "orthogonal meander patterns" are patterns whose center lines are orthogonal to each other.

[0020.] In the stent of FIGS. 1-4, the two meander patterns are labeled 11 and 12 and they are most easily seen in FIG. 2. Meander pattern 11 is a vertical sinusoid having a vertical center line 9. Meander pattern 11 has two loops 14 and 16 per period wherein loops 14 open to the right while loops 16 open to the left. Loops 14 and 16 share common members 15 and 17, where member 15 connects from one loop 14 to its following loop 16 and member 17 connects from one loop 16 to its following loop 14.

[0021.] Meander pattern 12 is an horizontal pattern having an horizontal center line 13. Meander pattern 12 also has loops, labeled 18 and 20, but between loops of a period is an extended straight section labeled 22. Loops 18 open downwards and loops 20 open upwards.

[0022.] Vertical meander pattern 11 is provided in odd and even (o and e) versions which are 180° out of phase with each other. Thus, each left opening loop 16 of meander pattern 11o faces a right opening loop 14 of meander pattern 11e and a right opening loop 14 of meander pattern 11o faces a left opening loop 16 of meander pattern 11e.

[0023.] Horizontal meander pattern 12 is also provided in odd and even forms. The straight sections 22 of horizontal meander pattern 12e intersect with every third common member 17 of vertical meander pattern 11e. The straight sections 22 of horizontal meander pattern 12o intersect with every third common member 15 of vertical meander pattern 11e, beginning with the common member 15 two after an intersected common member 17. The result is a full loop 14

between meander patterns 12e and 12o and a full loop 16 between meander patterns 12o and 12e.

[0024.] Returning to FIG. 1, the pattern of FIG. 2 is formed into a tube 30 of an easily deformable material, such as a metal. Due to the two meander patterns, the stent of FIG. 1, when attached over a catheter balloon, is flexible and can therefore be easily dragged through curved blood vessels. An example of the way in which the stent of FIG. 1 bends is illustrated in FIG. 3.

[0025.] In FIG. 3, the stent begins to bend at the point marked A in the direction marked by arrow 40. As the stent begins to curve, the section marked I becomes the inside of the curve while the section marked O becomes the outside of the curve. The inside of the curve I is shortened vis-a-vis the outside of the curve O.

[0026.] During bending, the loops 14-20 to the right of the point A change shape in order to compensate for the differences in length between the inside and outside curves. For example, loops 18i and 20i near the inside of the curve are closer together than loops 18o and 20o on the outside of the curve, which expand. Loops 14i and 16i near the inside I are compressed while the loops 14o and 16o closer to the outside O of the curve are expanded.

[0027.] As can be seen, both meander patterns 11 and 12 are involved in the bending. Although not shown, it will be appreciated that the stent of FIGS. 1-4 can bend in any direction and in more than one direction at any time.

[0028.] FIG. 4 illustrates the stent of FIG. 1 in its expanded form. When the stent expands, both meander patterns 11 and 12 expand (i.e. all loops 14-20 open up). As can be seen, the expanded stent has two types of enclosed spaces, a large space 42 between meander patterns 12o and 12e and a small space 44 between meander patterns 12e and 12o. As can also be seen, each large space 42 has two loops 14 on its left side and two loops 16 on its right side. The large spaces between vertical meander patterns 11e and 11o, which are labeled 42a, have loops 18 at their tops and bottoms while the large spaces between vertical meander patterns 11o and 11e,

which are labeled 42b, have loops 20 at their tops and bottoms. Similarly for small spaces 44a and 44b.

[0029.] It is noted that, due to the orthogonal meander patterns 11 and 12, the stent of FIG. 1 does not significantly shrink during expansion. This is illustrated in detail in FIGS. 5A and 5B to which reference is now made. FIG. 5A illustrates the movement, during expansion, of one vertical meander pattern 11 and FIG. 5B illustrates the movement, during expansion, of one horizontal meander pattern 12. The original patterns are shown with solid lines and the expanded patterns are shown with dashed lines.

[0030.] The vertical meander pattern 11 of FIG. 5A expands by widening its loops 14 and 16. As a result, the vertical meander pattern 11 grows vertically by an amount $2 \cdot h_1$ per loop. However, it also shrinks horizontally, by an amount $2 \cdot d_1$. Similarly, the horizontal meander pattern 12 of FIG. 5B expands by widening its loops 18 and 20. As a result, the horizontal meander pattern 12 grows horizontally by an amount $2 \cdot d_2$ per loop. However, it also shrinks vertically, by an amount h_2 . Thus, the vertical growth of the vertical meander pattern 11 compensates, at least partially, for the vertical shrinkage of the horizontal meander pattern 12, and vice versa. It is noted that the end portions of any stent are only partially compensated and therefore, may shrink somewhat.

[0031.] It will be appreciated that the two orthogonal meander patterns 11 and 12 and the compensation they provide to each other provides flexibility to the unexpanded stent of FIG. 1. However, when the stent is expanded, the changes in each of loops 14 and 16 provide rigidity to the resultant stent and thus, enable the stent to maintain a blood vessel at a desired inner diameter.

[0032.] The stent of the present invention can be manufactured from flat metal which is etched into the pattern of FIG. 2. The etched metal is then bent to form the tube 30. Alternatively, the pattern of FIG. 2 can be manufactured from welded or twisted wire.

[0033.] It will be appreciated that the stent of the present invention can be made from metal and/or wire. Additionally, it can be plated with a protective material, embedded with a medicine, and/or covered with a material which can fill in the spaces 42 and 44.

[0034.] It will be appreciated that the present invention encompasses all stents manufactured with a pattern formed of two meander patterns, orthogonal or otherwise. Another exemplary pattern, also with orthogonal meander patterns, is provided herein wherein FIG. 6 is a schematic version and FIG. 7 is a more rounded version. FIG. 8 shows the pattern of FIG. 7 in an expanded format. The pattern of FIGS. 6 and 7 is similar to that shown in FIG. 2 except that it has more horizontal meander patterns 12 and they are of one kind, rather than being even and odd as in FIG. 2.

[0035.] As can be seen in both FIGS. 6 and 7, there are two types of vertical meander patterns 11e and 11o which are 180° out of phase with each other. The horizontal meander patterns 12 connect with every line 15 of vertical meander pattern 11e.

[0036.] FIG. 8 illustrates the pattern of FIG. 7 is an expanded format. Since there are no even and odd horizontal meander patterns, in the expanded format of FIG. 8, there are no large and small spaces. Instead, all spaces are of the same size, i.e., the stent is comprised of a plurality of spaces or cells 50 defining a uniform cellular structure.

[0037.] As shown in FIGS. 3, 7 and 8, Applicants' invention can also be described as an expandable stent defining a longitudinal aperture 80 having a longitudinal axis or extension 79 and a circumferential axis or extension 105, including a plurality of flexible connected cells 50 with each of the flexible cells 50 having a first longitudinal end 77 and a second longitudinal end 78. Each cell 50 also is provided with a first longitudinal apex 100 disposed at the first longitudinal end 77 and a second longitudinal apex 104 disposed at the second longitudinal end 78. Each cell 50 also includes a first member 51 having a longitudinal component having a first

end 52 and a second end 53; a second member 54 having a longitudinal component having a first end 55 and a second end 56; a third member 57 having a longitudinal component having a first end 58 and a second end 59; and a fourth member 60 having a longitudinal component having a first end 61 and a second end 62. The stent also includes a first loop 63 defining a first angle 64 disposed between the first end 52 of the first member 51 and the first end 55 of the second member 54.

[0038.] A second loop 65 defining a second angle 66 is disposed between the second end 59 of the third member 57 and the second end 62 of the fourth member 60 and is disposed generally opposite to the first loop 63. A first flexible compensating member or flexible link 67 having a first end 68 and a second end 69 is disposed between the first member 51 and the third member 57 with the first end 68 of the first flexible compensating member or flexible link 67 communicating with the second end 53 of the first member 51 and the second end 69 of the first flexible compensating member or flexible link 67 communicating with the first end 58 of the third member 57. The first end 68 and the second end 69 are disposed a variable longitudinal distance 70 from each other.

[0039.] A second flexible compensating member 71 having a first end 72 and a second end 73 is disposed between the second member 54 and the fourth member 60. The first end 72 of the second flexible compensating member or flexible link 71 communicates with the second end 56 of the second member 54 and the second end 73 of the second flexible compensating member or flexible link 71 communicates with the first end 61 of the fourth member 60. The first end 72 and the second end 73 are disposed a variable longitudinal distance 74 from each other.

[0040.] In a preferred embodiment, the first and second flexible compensating member or flexible links 67 and 71 are arcuate. The first and second flexible compensating member or flexible links 67 and 71 are differentially extendable or compressible when the stent is bent in a curved direction away from the longitudinal axis 79 of the aperture 80. (Shown in FIG. 3.) The first member 51, second member 54, third member 57, and fourth member 60 and the first loop

63 and the second loop 65 and the first flexible compensating member or flexible link 67 and the second flexible compensating member or flexible link 71 are disposed so that as the stent is expanded the distance between the first flexible compensating member or flexible link 67 and the second flexible compensating member or flexible link 71 increases and the longitudinal component of the first member 51, second member 54, third member 57 and fourth member 60 decreases while the first loop 63 and the second loop 65 remain generally opposite to one another, the ends 68 and 69 of the first flexible compensating member or flexible link 67 and the ends 72 and 73 of the second flexible compensating member or flexible link 71 open so as to increase the variable longitudinal distance 70 between the first end 68 and the second end 69 of the first flexible compensating member or flexible link 67 and so as to increase the variable longitudinal distance 74 between the first end 72 and the second end 73 of the second flexible compensating member or flexible link 71. This compensates for the decreasing of the longitudinal component of the first member 51, second member 54, third member 57, and fourth member 60 and substantially lessens the foreshortening of the stent upon its expansion.

[0041.] In a preferred embodiment, and as shown in FIG. 5A, the flexible compensating member or flexible links 67 and 71 compensate in an amount that is substantially equal to the amount that the stent foreshortens. As shown in FIGS. 7 and 8, the first flexible compensating member or flexible link 67 and the second flexible compensating member or flexible link 71 in each cell 50 of each row or band of cells 101, 102 and 103, serve to flexibly connect other cells 50 in adjacent rows or bands 102, 103, and 104 which themselves have first and second compensating members 67 and 71.

[0042.] As shown in FIG. 7, the first flexible compensating member or flexible links 67 and 71 in row or band 101 serve to flexibly connect the cells 50 in adjacent rows or bands 102 and 103. As shown in FIGS. 7 and 8, a portion of the flexible member 67 or 71 disposed between the first ends 68 and 72 and the second ends 69 and 73 may be provided with a width that is smaller than the width of the apices 100 and 104 to which they are attached.

[0043.] It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined by the claims which follow: